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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,439	06/28/2004	Kyung-Jin Kim	PISI 2 00007	2416
27885	7590	05/16/2006	EXAMINER	
FAY, SHARPE, FAGAN, MINNICH & MCKEE, LLP 1100 SUPERIOR AVENUE, SEVENTH FLOOR CLEVELAND, OH 44114			WIEKER, AMANDA FLYNN	
			ART UNIT	PAPER NUMBER

3743

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/500,439

Applicant(s)

KIM, KYUNG-JIN

Examiner

Amanda F. Wieker

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 10-13 is/are rejected.
- 7) ☒ Claim(s) 3-9 and 14-20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 3,568,671 to Graham.

Graham discloses a combined splint and cast for immobilizing an injured body part comprising:

a foot fixing assembly (12) including an upper foot fixing member (24 and 32) and a lower foot fixing member (18 of 12) which together form a pair fully capable of immobilizing a region from the sole to a portion above the ankle of a foot;

a connecting assembly (14) including an upper connecting member (24) and a lower connecting member (18 of 14) which together form a pair fully capable of immobilizing a region from the ankle to the portion below the knee; and

a knee fixing member (16) fully capable of immobilizing the region from a knee to the middle portion of a femur,

wherein the foot fixing assembly, the connecting assembly and the knee fixing member can be used separately or at least two adjacent ones of the foot fixing assembly, the connecting assembly and the knee fixing member are used cooperatively by being fastened together.

*Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 3,568,671 to Graham in view of U.S. Patent Number 3,762,405 to De George.

Graham discloses a combined splint and cast for immobilizing an injured body part comprising:

a foot fixing assembly (12) including an upper and lower foot fixing member s(24 and 32; 18) which form a pair fully capable of immobilizing a region from the sole of a foot to a portion above an ankle;

a connecting assembly (14) including upper and lower connecting members (24; 18) which form a pair fully capable of immobilizing a region from the ankle to the portion below the knee; and

a knee fixing member (16) fully capable of immobilizing the region from a knee to a middle portion of a femur,

wherein the foot fixing assembly, the connecting assembly and the knee fixing member are capable of being used individually or cooperatively by being coupled to each other.

Graham discloses the previously described combined splint and cast comprising a foot fixing assembly having upper and lower foot fixing members, and a connecting assembly having upper and lower connecting members. Graham does not specify that the upper and lower foot fixing members, or the upper and lower connecting members, are discrete elements.

However, at the time the invention was made, it would have been an obvious matter of design choice to one of ordinary skill in the art to have made the upper and lower foot fixing members, and the upper and lower connecting members, as discrete elements, or in any other selected configuration, because Applicant has not disclosed that such a configuration provides an advantage, is used for a particular purpose, or solves a stated problem. A thorough reading of the specification provides no criticality to the discreteness of these members. One of ordinary skill in the art, furthermore, would have expected Graham's orthosis and Applicant's invention to perform equally well with either the unitary members used by Graham, or the claimed discrete members because both materials would perform the same function of immobilizing the desired body portion.

Therefore, it would have been *prima facie* obvious to modify Graham to obtain the invention as specified in the claims because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Graham.

Regarding claim 2, Graham discloses each and every structural element of the orthosis set forth in claim 2. Graham discloses a foot fixing assembly, a connecting assembly and a knee fixing member, but is silent as to the method of making these splint members. The claimed phrase "are injection molded" is being treated as a product by process limitation; that is, that the foot fixing member, connecting member and knee fixing members are made by injection molding.

As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Thus, even though Graham is silent as to the process used to make the splint members, it appears that the product in Graham would be the same or similar as that claimed; especially since both applicant's product and the prior art product are made of rigid materials intended to immobilize the limb.

In the alternative, it would have been obvious to one skilled in the art at the time the invention was made to have provided the splint disclosed by Graham, wherein the splint members are formed by injection molding, as taught by U.S. Patent Number 3,955,565 to Johnson, to accurately custom form a splint to fit a desired body portion.

5. Claims 10 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graham in view of U.S. Patent Number 3,762,405 to De George.

Graham discloses the previously described (paragraphs 2 and 4) combined splint and cast for immobilizing an injured body part comprising: a foot fixing assembly, a connecting assembly (14) and a knee fixing member (16), wherein the foot fixing assembly, the connecting assembly and the knee fixing member can be used separately or at least two adjacent ones of the foot fixing assembly, the connecting assembly and the knee fixing member are used cooperatively by being fastened together. Graham does not specify that bolts fasten the splint members to each other.

De George discloses a combined splint assembly for immobilizing an injured body part, wherein splint members are coupled to each other with bolts, to provide a secure connection.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the splint disclosed by Graham, wherein the splint members are coupled by bolts, as taught by De George, to provide a secure connection.

Regarding claim 13, Graham in view of De George disclose each and every structural element of the orthosis set forth in claim 13. Graham discloses a foot fixing member, a connecting member and a knee fixing member, but is silent as to the method of making these splint members. The claimed phrase "are injection molded" is being treated as a product by process limitation; that is, that the foot fixing member, connecting member and knee fixing members are made by injection molding.

As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 U.S.C. 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Thus, even though Graham is silent as to the process used to make the splint members, it appears that the product in Graham would be the same or similar as that claimed; especially since both applicant's product and the prior art product are made of rigid materials intended to immobilize the limb.

In the alternative, it would have been obvious to one skilled in the art at the time the invention was made to have provided the splint disclosed by Graham in view of De George, wherein the splint members are formed by injection molding, as taught by U.S. Patent Number 3,955,565 to Johnson, to accurately custom form a splint to fit a desired body portion.

*Allowable Subject Matter*

6. Claims 3-9 and 14-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Response to Arguments*

7. Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

*Conclusion*

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda F. Wieker whose telephone number is 571-272-4794. The examiner can normally be reached on Monday-Thursday, 7:30 - 5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
afw

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